



## EUROPEAN COMMISSION

Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

Resources Based, Manufacturing and Consumer Goods Industries  
Health Technology and Cosmetics

### SCIENTIFIC COMMITTEE ON CONSUMER SAFETY (SCCS)

**Request for a scientific opinion:** Submission III on Polyaminopropyl Biguanide (PHMB) (CAS 32289-58-0 / 27083-27-8 / 28757-47-3 / 133029-32-0).

**Commission Department requesting the Opinion:** Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

#### 1. Background

Poly(hexamethylene) biguanide hydrochloride (PHMB) (CAS 32289-58-0 / 27083-27-8 / 28757-47-3 / 133029-32-0) with INCI name Polyaminopropyl Biguanide, is currently listed in Annex V (entry 28) of the Regulation (EC) No. 1223/2009<sup>1</sup> (Cosmetics Regulation) as preservative to be used in all cosmetic products up to a maximum concentration of 0.3%.

Polyaminopropyl Biguanide (PHMB) is classified as CMR 2 (Carc. 2) according to the Commission Regulation (EU) No. 944/2013<sup>2</sup> of 2 October 2013 amending for the purposes of its adaptation to technical and scientific progress the Regulation (EC) No. 1272/2008<sup>3</sup>. The classification applies from 1<sup>st</sup> January 2015.

Article 15 (1) of the Cosmetics Regulation states that '*a substance classified in category 2 may be used in cosmetic products where the substance has been evaluated by the SCCS and found safe for use in cosmetic products. To these ends the Commission shall adopt the necessary measures in accordance with the regulatory procedure with scrutiny referred to in Article 32(3) of this Regulation*'.

The SCCS published an opinion on the safety of PHMB in June 2014 successively revised in July 2015 (SCCS/1535/14)<sup>4</sup> in which they concluded that:

*"Polyaminopropyl Biguanide (PHMB) is not safe for consumers when used as a preservative in all cosmetic products up to the maximum concentration of 0.3%.*

*The safe use could be based on a lower use concentration and/or restrictions with regard to cosmetic products' categories. Dermal absorption studies on additional representative cosmetic formulations are needed.*

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<sup>1</sup> <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:342:0059:0209:en:PDF>

<sup>2</sup> <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:261:0005:0022:EN:PDF>

<sup>3</sup> <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:353:0001:1355:en:PDF>

<sup>4</sup> [http://ec.europa.eu/health/scientific\\_committees/consumer\\_safety/docs/sccs\\_o\\_157.pdf](http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_157.pdf)

*On the basis of the data available, the SCCS concludes that Polyaminopropyl Biguanid ((PHMB) is not safe for consumers when used as a preservative in cosmetic spray formulations up to concentration of 0.3%.*

*PHMB is used in a variety of applications other than cosmetics. General exposure data from sources others than cosmetics should be submitted for the assessment of the aggregate exposure of PHMB."*

In May 2016, Cosmetics Europe transmitted a new safety dossier on PHMB that addresses the major issues raised by the SCCS notably i) a lower maximum concentration of 0.1%, ii) new dermal absorption studies on representative formulations and iii) aggregate exposure data.

## **2. Terms of reference**

- (1) *In light of the new data provided, does the SCCS consider Polyaminopropyl Biguanide (PHMB) safe when used as preservative in all cosmetic products up to a maximum concentration of 0.1%?*
- (2) *Alternatively, taking into account the EU market data available, does the SCCS consider Polyaminopropyl Biguanide (PHMB) safe when used as preservative up to a maximum concentration of 0.1% in all cosmetic products with the exclusion of those products categories (body lotion, hand cream and oral care) in which this ingredient is seldom used?*
- (3) *According to the new data provided, does the SCCS consider Polyaminopropyl Biguanide (PHMB) safe for use in sprayable formulations up to a maximum concentration of 0.1%?*
- (4) *Does the SCCS have any further scientific concerns with regard to the use of Polyaminopropyl Biguanide (PHMB) in cosmetic products?*

**3. Deadline:** December 2016

## **4. Supporting documents:**

1. Dossier on the Safety of Poly(hexamethylene) biguanide hydrochloride or Polyaminopropyl Biguanide (PHMB) (CAS Nos. 32289-58-0 or 27083-27-8) in Cosmetic Products . Cosmetics Europe. 30 May 2016
2. Folder Reference.zip
3. Folder Further Studies